REMARKS

Claims 1-43 were present in the application and stand rejected. As set forth above, Claims 1, 5, 6, 13, 16, 18, 23, 31, 35 and 40 have been amended and Claims 8, 14 and 17 have been canceled. Claims 1, 23 and 40 have been amended to provide that the cleanser comprises from about 1 mM to about 250 mM of a chelating agent, a pH buffer for maintaining the pH of the cleanser in the range of 7.0 to 9.0, and from about 1 to about 30% by volume of cocamidopropyl betaine, and that the concentrations of the chelating agent and the cocamidopropyl betaine are selected to allow the chelating agent and the cocamidopropyl betaine to synergistically enhance the antimicrobial activity of the skin cleanser Support for these amendments is found in the specification at page 10, lines 6-15, and elsewhere. It is believed that amended Claims 1-7, 9-13, 15, 16 and 18-43 are in condition for allowance in view of the following comments. Reconsideration and favorable action is requested.

Double Patenting

The Examiner has provisionally rejected Claims 1-7, 9-19, 23, 24 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 9, 11-34, 43-47, 51-60,6 5-74 and 76-78 of copending Application No. 10/739,841. The claims of the present application are directed to skin cleansers, methods of cleansing skin and kits therefore. The claims of copending Application No. 10/739,841 are directed to methods, compositions and kits for wound management.

In addition, the Examiner has provisionally rejected Claims 24-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 2, 5-15, 18-22 and 56-62 of copending Application No. 09/955,657. The claims of Application No. 09/955,657 are directed to methods of inhibiting proliferation of a bacterial population of a skin injury or surface lesion.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

Since Application Nos. 10/739,841, 09/955,657 and the current application are subject to rejection(s) on other grounds, this rejection will be addressed when nonstatutory obviousness-type double patenting is the only rejection remaining pursuant to MPEP §804.

Rejection of Claims Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-6, 9, 11, 17, 19, 23, 24, 26-31, 37 and 39 under 35 U.S.C. § 102 as being anticipated by Mulder U.S. Patent No. 5,565,189 (the "Mulder '189 patent"). The Examiner has cited the Mulder '189 patent as teaching a method of cleaning the skin comprising the application of a cleansing composition comprising a carrier, water and aloe vera gel, a pH buffer such as sodium borate, chelators such as EDTA, vitamin E, surfactants such as cocamphoacetate and biocides such as hydroxyquinoline (citing example 1). The Examiner has further cited the Mulder '189 patent as disclosing debriding the wound site and rinsing the composition after it is applied (citing Column 4, lines 45-55), having a pH of the composition between pH 6.5-6.8 (citing Column 4, lines 3-10), and including sensitizers that relieve pain (citing example 1).

The Mulder '189 patent discloses a non-sensitizing over-the-counter wound cleanser composed of a carrier portion (70-90 wt% of the cleanser; Column 2, lines 28-35), an emollient portion (up to 10 wt% of the cleanser; Column 2, lines 36-46), a humectant portion (up to 10 wt% of the cleanser; Column 2, lines 47-53), a surfactant portion (up to 10 wt% of the cleanser; Column 2, lines 54-60), a preservative portion (up to 1.5 wt% of the cleanser; Column 2, lines 54-60), and a cosmetic biocide (oxyquinoline, up to 2 wt% of the cleanser; Column 3, lines 3-4).

The carrier portion of the cleanser includes 65-75 wt% of water and 7-13 wt % of aloe vera gel based on the total weight of the cleanser (Column 2, lines 30-32).

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS[PLLC]
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

The emollient portion is an alkyl stearate, preferably butyl stearate (Column 2, lines 38-42), but may be cetyl, isobutyl, isocetyl, isopropyl, myristal or octyl stearate (Column 2, lines 42-43).

The humectant is glycerine (Column 2, lines 51-53; Table 1, Column 4, line 36).

The surfactant portion is cocamphoacetate (Column 2, lines 57-60; Table 1, Column 4, line 41).

The preservative portion is 0.08-0.12 wt % sodium EDTA or 0.7-1.2 wt % alkyl paraben (Column 2, lines 26, 27, and 63-67; Table 1, Column 4, lines 38 and 39).

The cosmetic biocide portion is hydroxyquinoline, an antiseptic with mild fungistatic, bacteriostatic, anthelmintic, and amebicidal action.

In addition, the cleanser of the Mulder '189 patent may contain an alkalizer (up to 1% (wt/wt) triethanolamine or sodium borate; Column 4, lines 12-14) or an acid/conjugate base buffering system, to maintain the pH of the cleanser within the range of 6.5 to 6.8; vitamin E (up to 1 wt% of the cleanser; Column 3, lines 16-18) to assist in reepithelialization of a wound site; and cocamide DEA (up to 5 wt% of the cleanser; Column 3, lines 19-22) to act as a viscosifier.

As set forth above, Claims 1 and 23 have been amended to require that the cleanser comprise from about 1 mM to about 250 mM of a chelating agent, a pH buffer for maintaining the pH of the cleanser in the range of 7.0 to 9.0, and from about 1 to about 30% by volume of cocamidopropyl betaine. Dependent Claims 2-6, 9, 11, 17, 19, 24, 26-31, 37 and 39 also inherently contain these limitations.

In view of the foregoing amendments, Claims 1-6, 9, 11, 17, 19, 23, 24, 26-31, 37 and 39 cannot be anticipated under 35 U.S.C. § 102(b) by the Mulder '189 patent. In addition, as set forth in detail in the application and in independent Claims 1 and 23, the concentrations of the chelating agent and the cocamidopropyl betaine are selected to allow the chelating agent and the

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

cocamidopropyl betaine to synergistically enhance the antimicrobial activity of the skin cleanser. This aspect of applicants' invention is demonstrated in Example 8 of the application. Since the Mulder '189 patent contains no disclosure or remote suggestion of this aspect of applicants' invention, Claims 1-6, 9, 11, 17, 19, 23, 24, 26-31, 37 and 39 cannot be obvious under 35 U.S.C. § 103 over the Mulder '189 patent disclosure. Accordingly, the rejection of Claims 1-6, 9, 11, 17, 19, 23, 24, 26-31, 37 and 39 over the Mulder '189 patent should properly be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1, 7, 8, 12-16, 18, 25, 32-36 and 38 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of the Mulder '189 patent in view of both Steel et al. U.S. Patent No. 6,224,853 (the Steel et al. '853 patent) and Huber et al. U.S. Patent No. 3,758,682 (the Huber et al. '682 patent). The Examiner has cited the Steel et al. '853 patent as disclosing an aqueous formulation comprising lanolin and further cosurfactants such as cocamidopropyl betaine and lecithin where the surfactant is present in a concentration from 1-25% (citing Column 4, lines 18-39, Column 5, lines 20-45; Column 6, lines 40-50). The Examiner has cited the Huber et al. '682 patent as disclosing a formulation useful in wound healing comprising a buffer solution comprising tris(hydroxymethyl) amino methane (citing Column 13; lines 25-30), and that the composition can be administered orally contacting the oral mucosa (citing Column 24, lines 19-53).

The Steel et al. '853 patent discloses an aqueous emulsion composition useful as a carrier for transdermal delivery of pharmaceutical actives to the human skin comprising water and (a) one or more surfactant materials selected from polyoxyalkylene condensate derivatives of lanolin or a lanolin derivative and (b) a lipid component comprising one or more lipid materials present as particles having a median particle size of less than about 5μ, emulsified by the lanolin-derived surfactant materials. At Column 4, lines 40-49, the Steel et al. '853 patent discloses:

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

> The compositions of the invention may optionally additionally contain one or more co-surfactant materials, which may be selected from various natural, synthetic or semi-synthetic surface active substances capable of forming in the aqueous phase a matrix structure within which the other ingredients are dispersed. Such co-surfactants may serve as additional emulsifying agents for the lipid component and/or may be useful to adjust the overall physical properties of the compositions, e.g. in order to optionally suit particular end-uses. [Emphasis added.]

At Column 5, lines 29 and 30, the Steel et al. '853 patent discloses that a suitable co-surfactant (i.e., as an additional emulsifying agent) may be cocamidopropyl betaine. However, the Steel et al. '853 patent does not disclose or suggest a cleaner comprising from about 1 mM to about 250 mM of a chelating agent, a pH buffer for maintaining the pH of the cleanser in the range of 7.0 to 9.0, and from about 1 to about 30% by volume of cocamidopropyl betaine, or that the concentrations of the chelating agent and the cocamidopropyl betaine are selected to allow the chelating agent and the cocamidopropyl betaine to synergistically enhance the antimicrobial activity of the skin cleanser, as required by applicants' amended claims.

Although the Steel et al. '853 patent discloses lanolin-derived surfactant materials for use as a carrier of active pharmaceuticals in transdermal delivery of the pharmaceuticals, it does not overcome the deficiencies of the disclosure of the Mulder '189 patent, as discussed in detail above. Accordingly, Claims 1, 7, 8, 12-16, 18, 25, 32-36 and 38 would not have been obvious under 35 U.S.C. §103(a) over the combined disclosure of the Mulder '189 patent in view of the Steel et al. '853 patent, and this rejection should properly be withdrawn.

The Huber et al. '682 patent discloses pharmaceutical compositions comprising orgotein for ameliorating the adverse effects of inflammatory conditions, of stress conditions, including shock and toxemia, and of certain viral diseases. Although the Huber et al. '682 patent discloses the use of buffers including tris(hydroxymethyl) amino methane in a pharmaceutical composition, it does not disclose or remotely suggest a cleaner comprising from about 1 mM to about 250 mM of a chelating agent, a pH buffer for maintaining the pH of the cleanser in the

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

range of 7.0 to 9.0, and from about 1 to about 30% by volume of cocamidopropyl betaine, or that the concentrations of the chelating agent and the cocamidopropyl betaine are selected to allow the chelating agent and the cocamidopropyl betaine to synergistically enhance the antimicrobial activity of the skin cleanser, as required by applicants' amended claims. and does not overcome the deficiencies of the disclosure of the Mulder '189 patent or the Steel et al. '853 patent, as discussed in detail above. Accordingly, Claims 1, 7, 8, 12-16, 18, 25, 32-36 and 38 would not have been obvious under 35 U.S.C. §103(a) as being unpatentable over the Mulder '189 patent in view of the Huber et al. '682 patent, and this rejection should properly be withdrawn.

The Examiner has further rejected Claims 1, 4, 10 and 20 under 35 U.S.C. § 103(a) as being unpatentable over the Mulder '189 patent in view of Robertson et al. U.S. Patent No. 4,939,135 (the Robertson et al. '135 patent). The Examiner has relied on the Robertson et al. '135 patent as disclosing a wound healing formulation and method of applying the formulation to an ocular injury (citing the abstract), the formulation comprising anti-inflammatory agents such as dexamethasone and antimicrobials such as neomycin and vancomycin (citing Column 4, lines 60-65, and Column 9, lines 60-68). The active agents are in a concentration from 0.5-1.0% of the total formulation (Column 8, lines 1-5). The formulation further comprises chelators and sorbic acid (Column 10, lines 60-65). The Examiner has concluded that an artisan of ordinary skill would be motivated to combine the components of the Mulder '189 patent with those of the Robertson et al. '135 patent since they both solve the same problem of wound management with cleansing compositions.

The Robertson et al. '135 patent is directed to compositions and methods for the treatment of corneal haze resulting from photoblation of the cornea during ophthalmic surgery. Agents used in the compositions include steroids, growth factors, basement membrane components, anti-oxidants, regulators of collagen structure, aldose reductase inhibitors, nonsteroidal

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

antiinflammatories, immunomodulators, antiallergics, fatty acid derivatives which are products of the arachidonic acid cascade and antimicrobials (see Column 3, lines 16-35). Although the Robertson et al. '135 patent discloses at Column 10, lines 54-64, that in addition to the principal active ingredients, the disclosed wound healing modulator compositions may optionally further comprise from about 0.0001 wt. % to 1.0 wt. % of various antimicrobial preservatives, such as EDTA, the Robertson et al. '135 patent does not disclose or suggest a cleaner comprising from about 1 mM to about 250 mM of a chelating agent, a pH buffer for maintaining the pH of the cleanser in the range of 7.0 to 9.0, and from about 1 to about 30% by volume of cocamidopropyl betaine, or that the concentrations of the chelating agent and the cocamidopropyl betaine are selected to allow the chelating agent and the cocamidopropyl betaine to synergistically enhance the antimicrobial activity of the skin cleanser, as required by applicants' amended claims. Accordingly, the Robertson et al. '135 patent does not overcome the deficiencies of the disclosure of the Mulder '189 patent, as discussed in detail above, and Claims 1, 4, 10 and 20 would not have been obvious under 35 U.S.C. § 103(a) over the Mulder '189 patent in view of the Robertson et al. '135 patent.

The Examiner has further rejected Claims 1, 21 and 22 under 35 U.S.C. § 103(a) over the combined disclosures of the Mulder '189 patent in view of Gehlsen U.S. Patent No. 6,270,781 (the Gehlsen '781 patent). Claims 21 and 22 relate to the skin cleanser of Claim 1 which further comprise a colorant or a perfume, respectively. The Examiner has cited the Gehlsen '781 patent as disclosing a topical skin composition comprising detergents, antimicrobial agents, perfumes and pigments (citing Column 8, lines 6-15; Column 8, lines 57-65; and Column 9, lines 28-32). It is the Examiner's position that an artisan of ordinary skill would have been motivated to include the pigments and perfumes of the Gehlsen '781 patent with the formulation of the Mulder '189 patent since they comprise similar components in the same field of endeavor.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

The Gehlsen '781 patent discloses topical formulations containing compounds that reduce or inhibit the amount of reactive oxygen metabolites (ROMs) and secondary cytokines produced or released by sources within a subject to facilitate the treatment of individuals suffering from a variety of skin and mucosal conditions, such as herpes infections and photodermatitis. Although the Gehlsen '781 patent discloses that its compositions containing its ROM inhibitory compounds may contain colorants or perfumes, it does not disclose or suggest the skin cleansers of applicants' amended claims, and does nothing to overcome the deficiencies of the Mulder '189 patent, discussed in detail above. Accordingly, Claims 1, 21 and 22 would not have been obvious under 35 U.S.C. § 103(a) over the Mulder '189 patent in view of the Gehlsen '781 patent.

The Examiner has additionally rejected Claims 40-43 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of the Mulder '189 patent in view of Horn U.S. Patent No. 5,848,700 (the "Horn '700 patent"). Claims 40-43 relate to kits container the skin cleanser of applicants' amended claims. The Examiner has cited the Horn '700 patent as disclosing a kit comprising instructions for various applications methods including cleansing the skin of burns, cuts, wounds and fractures (claims). It is the Examiner's position that it would have been obvious to include the skin cleanser of the Mulder '189 patent with the instructions of the Horn '700 patent, since they both endeavor to treat wounds.

The Horn '700 patent discloses an emergency medical care kit that comprises a carrying case approximately the size of a briefcase or small suitcase with the upper and lower sections divided into a large number of compartments by insertion of a plastic organizer with removable covers. The reverse side of each compartment cover has instructions for treating the particular emergency, while the compartment itself contains the necessary care items for that particular emergency. A hinged divider is held by snaps across the upper section of the case to help

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

contain the contents and also provides instruction for use of the kit, some general first aid information, and a list of emergency telephone numbers.

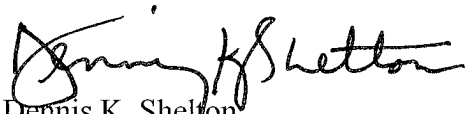
Although the Horn '700 patent discloses a kit for medical emergencies, it does not disclose or remotely suggest the skin cleansers of applicants' amended claims, and does not overcome the deficiencies of the Mulder '189 patent discussed in detail above. Accordingly, Claims 40-43 would not have been obvious under 35 U.S.C. § 103(a) over the Mulder '189 patent in view of the Horn '700 patent.

Conclusion

In view of the foregoing amendments and comments, Claims 1-7, 9-13, 15, 16 and 18-43 are believed to be in condition for allowance. Reconsideration and favorable action is requested. The Examiner is further requested to contact the applicants' representative by telephone to discuss any issues that may facilitate prosecution of the application.

Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON KINDNESS[PLLC]



Dennis K. Shelton
Registration No. 26,997
Direct Dial No. 206.695.1718

DKS:DKS

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS[PLLC]
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100